MARYLAND COMMISSION ON KIDNEY DISEASE

THE CONNECTION

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CHAIRMAN'S REPORT

During the past year, we have experienced some weather-related challenges that bring into focus, once again, the need for always being prepared to deal with emergencies in operating our dialysis units.

It is important to have alternative plans for the provision of dialysis, making sure our patients are safely managed when they see their regular dialysis schedules disrupted by weather related emergencies. Also educating them about what to do with their diet as it pertains to fluid and Potassium restriction goes a long way to make our and their lives easier.

Another issue that I would like to bring up is the need to always have our patients with native fistulas, be educated and prepared on how to deal with the rare but serious instance of sudden bleeding from the access when they are not at the dialysis units. As you know protracted bleeding will lead to death in minutes.

Speaking of safety, I do believe that a culture of Safety has to start from the top down. And this rests right on with the role of the Medical Director, who is ultimately responsible for the overall care delivered in the dialysis Unit.

During my years as a Chairman of the Kidney Commission, I have had many times the opportunity to be involved in addressing problems/ deficiencies with the senior Staff and management of a Dialysis Unit. More often than not, I have been stricken by the lack of involvement and accountability by the Medical Director in addressing the specific deficiencies. This tells me

that if there is no proactive and ongoing involvement by the Medical Director in setting up the tone and standards to implement a culture of safety, the quality of care at any given facility will suffer. Sometimes it is a glaring issue of lack of communication. The Medical Director is not fully debriefed by the management staff and thus he is not aware of the problems. At other times the Medical Director seems to be disinterested.

I cannot be more emphatic in reminding my Fellow physicians and colleagues who are Medical Directors, how important it is to be involved and to set the proper tone for the quality of care that you would like and expect to see in your units.

Lately, we have been busy lately looking at the drug formulary covered by Kidney Disease Program (KDP). We want to make sure that our patients have access to the latest drugs to help the management of ESRD and transplantation, but this has to be tempered by the limited financial resources made available to the program by the State of Maryland. Sometimes we may not be able to cover certain drug due to cost issues. We need to make sure that every enrollee in the program has equal access and to have some of their medications covered by the program.

We have also begun to look at our procedures for monitoring the quality and compliance with established policies and guidelines in operating our dialysis units. Continued on Page 3

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COMMISSION MEETINGS



The Commission on Kidney Disease will meet on the following dates in 2016:

April 21, 2016 July 28, 2016

October 27, 2016
The Commission meets at the Department of Health and

Mental Hygiene, 4201 Patterson Avenue Baltimore, MD 21215. The Open Session of the meeting begins at 2:00pm and is open to the public. For further information regarding these meetings, please contact the Commission office at (410) 764 - 4799. PAGE 2 THE CONNECTION

COMMISSION NEWS

CITATION FREE SURVEYS

The Commission is commending a record number of facilities for achieving citation free surveys:

University of Maryland Transplant Center

Johns Hopkins Transplant Center

Western Maryland Regional Dialysis

IDF Garrett Center

Davita PG South

USRC West Baltimore

Deer's Head Hospital Dialysis

Davita Berlin

Davita Baltimore Geriatric Center

Holy Cross Hospital Dialysis

IDF Chestnut Center

ARA Ellicott City

IDF Arundel Center

Davita Landover

Davita Owings Mills

Good Samaritan Manor Care

Davita Pasadena

Davita Dundalk

Davita Queen Anne Home Training

FMC Middle River

IDF Parkview Center

Davita Carroll County

FMC Odenton

Johns Hopkins Harriet Lane

It is an achievable goal, and should be the goal of each facility.

CONGRATULATIONS!



FACILITIES APPLYING FOR CERTIFICATION

The following facilities have applied for certification with the Commission, for KDP reimbursement purposes:

- Davita Forestville
- Good Samaritan North Point
- NxStage Baltimore West

The above stated facilities have been certified and are in good standing with the Commission.

COMMISSION WEBSITE

www.dhmh.maryland.gov/mdckd

Find the latest Commission information: meeting dates, new facility information, complaint forms, regulations, Governor's report and past and current newsletters.

HISTORY IN THE MAKING!

Johns Hopkins Performs the First H.I.V.-Positive Organ Transplants in the U.S.

In March, Johns Hopkins performed the first kidney and liver transplants between H.I.V.-positive donors and H.I.V.-positive patients in the United States, a development that could create a lifesaving conduit for H.I.V. patients, and in turn help shorten the overall organ donor waiting lists.

This comes after a multi-year effort led by Dr. Dorry Segev to change the law and allow transplantation of H.I.V.-positive organs (which was specifically prohibited by the National Organ Transplant Act in the 1980's). The journey started with a landmark scientific paper published by Dr. Segev and his team five years ago quantifying the potential H.I.V.-positive donor pool. They then drafted a congressional bill (The HIV Organ Policy Equity or HOPE Act) and strategically lobbied patient advocacy groups and legislators. The HOPE Act was one of only 57 bills passed in 2013. It requires transplantation of HIV positive organs through an NIH approved protocol. This is being conducted under an NIH funded research study, with multidisciplinary teams that include Transplant Infectious Disease, Transplant Surgery, Transplant Nephrology, Pathology and many others.

Advances in diagnosis and treatment has transformed H.I.V. from a lethal illness into a chronic disease managed with antiretroviral drugs. H.I.V.-infected patients are now more likely to face other chronic conditions common among non-infected people, including liver and kidney failure, for which organ transplants are the standard of care, but many die waiting for an organ to become available.

It's estimated that organs from 500 to 600 H.I.V.-positive potential donors have gone to waste each year and that allowing those donations could save more than 1,000 people.

This is an excellent example of the linkage between research, policy and clinical practice where Hopkins Transplant has demonstrated leadership within the field. From kidney paired donation, to now the HOPE Act, our group's work continues to address one of the biggest challenges in transplantation — expansion of the donor pool.

By: Laura Conroy, RN, BSN

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"Take Five for Your Kidneys"

As the 9th leading cause of death in the United States, kidney disease kills more people every year than breast cancer or prostate cancer. The National Kidney Foundation recommends taking five healthy steps for your kidneys:

- 1. Get Tested! Ask your doctor for an ACR urine test or a GFR blood test annually if you have diabetes, high blood pressure, are over age 60, or have a family history of kidney failure. The National Kidney Foundation of Maryland (NKF-MD) offers free kidney health screenings throughout the year. To locate a screening near you, visit www.kidneymd.org.
- 2. Reduce NSAIDs. Over the counter pain medicines, such as NSAIDs (nonsteroidal anti-inflammatory drugs), may alleviate your aches and pains, but they can harm the kidneys, especially if you already have kidney disease. Reduce your regular use of NSAIDs and never go over the recommended dosage.
- **3. Cut the Processed Foods.** Processed foods can be significant sources of sodium, nitrates and phosphates, and have been linked to cancer, heart disease and kidney disease. Try adopting the DASH Diet to guide your healthy eating habits.
- 4. Exercise Regularly. Your kidneys like it when you exercise. Regular exercise will keep your bones, muscles, blood vessels, heart and kidneys healthy. Getting active for at least 30 minutes a day can also help you control blood pressure and lower blood sugar, which is vital to kidney health.
- 5. Stay Well Hydrated. Staying well hydrated helps your kidneys clear sodium, urea and toxins from the body. Drinking plenty of water, and avoiding sugary beverages, is also one of the best ways to avoid painful kidney stones. Those with kidney problems or kidney failure may need to restrict their fluid intake, but for most people, drinking 1.5 to 2 liters (3 to 4 pints) of water per day is a healthy target.

Addition of New Drugs to the KDP Formulary

The Kidney Disease Program maintains a formulary of drugs approved for coverage. The goal of the program is to provide the appropriate care for patients with ESRD (end-stage kidney disease defined by their need for dialysis and/or kidney transplantation) that is consistent with current guidelines and safe. The formulary includes therapeutic agents used for therapy of conditions that are caused by the development of chronic kidney disease and/or in the setting of ESRD will contribute to the progressive decline of health and/ or increased risk of death for KDP recipients. The formulary cannot be all inclusive and therefore therapeutic agents used for medical problems not linked to chronic kidney disease or problems associated with it are not included. Drugs included in the formulary are periodically reviewed for efficacy (guidelines have changed over time) and safety. This is done by the members of the Kidney Commission at times with expert consultation. Those agents found not to be safe or efficacious are then removed.

The Kidney Commission (its administrators and the members) are often asked how new drugs can be added to the formulary. The Kidney Commission is responsible to assess the advantages/disadvantages and safety of any drug that potentially could be placed on the formulary and then based on this analysis to make a recommendation to the Kidney Disease Program. The process by which a drug is considered includes:

A request to consider a new drug for the formulary is received by the Kidney Commission. We recommend sending a letter or email to the Kidney Commission office. The Kidney Commission administrators will then contact the Kidney Commissioners to begin a review of the therapeutic agent.

Material supporting the addition of the drug must be submitted to the Kidney Commission Office before a review by the Commissioners can be initiated. This information must include:

A letter that outlines the rationale for inclusion of the drug. This should include information about how the drug is used for care of patients with ESRD and how the drug is more efficacious then current drugs currently included in the formulary.

Published unbiased references that include well designed trials that demonstrate the efficacy and safety of the proposed drug (Phase 3 and Phase 4 trials if available)

Information from the manufacturer about cost.

If the Kidney Commissioners determine that the drug is either unique or equally or more efficacious than current drugs on the formulary for care of patients covered by KDP, they will request that the KDP add the drug to the formulary. (The Kidney Commissioners do evaluate the cost for drugs that are felt to be equally efficacious with current drugs on the formulary when they determine their recommendation.)

The drug will only be included in the formulary:

The documentation received and reviewed by the Kidney Commission demonstrates that the drug's availability is essential to KDP recipients (process outlined above). This information will be forwarded to the Secretary of the Maryland Department of Health and Mental Hygiene (DHMH) for final approval.

The manufacturer participates in the rebate program of the Maryland State-Only Pharmacy Assistance Program and offer the same rebate to the KDP or submit a request for a waiver from the rebate requirement, which has then been approved.

By: Edward Kraus, M.D.

Chairman's Report

(Continued from Page 1)

We think that if a citation is necessary to bring up a noted deficiency, the process should not stop with the submission of a facility's plan of correction.

We believe that there should be a mechanism in place for following-up the progress made regarding the implementation of the plan of correction. At this time, we do not have a solution for this but we would like to engage the dialysis community in giving us feedback as to how to implement this without a significant disruption in the day to day operation of the dialysis unit.

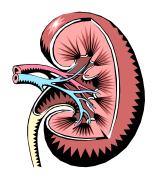
By: Luis Gimenez, M.D.

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WE ARE ON THE WEB dhmh.maryland.gov/mdckd/

NATIONAL KIDNEY FOUNDATION

Free Kidney Health (KEY) Screenings & Assessments

Saturday, April 2, 2016

Peninsula Regional Medical Center HealthFest James M. Bennett High School 07:30 am - 1:00 pm 300 East College Avenue, **Salisbury, MD**

Saturday, October 1, 2016

7th Hispanic Health Festival & Resources Heritage Community Church 10:00 am - 2:00 pm 8146 Quarterfield Road, **Severn, MD**

Sunday, October 23, 2016

Mount Pleasant Church & Ministries Go Pink, Go Blue Health Fair Expo 12:00 pm - 3:00 pm 6000 Radecke Avenue, **Baltimore**, **MD**

Greater Baltimore Kidney Walk

Sunday, April 17, 2016
9:00 am Check In; 10:00 am Walk Start
Camden Yards Sports Complex,
Baltimore, MD

Southern Delaware Kidney Walk

Sunday, April 24, 2016 10:00 am Check In; 12:00 pm Walk Start Cape Henlopen State Park, Lewes, DE

Salisbury Kidney Walk

Sunday, May 15, 2016 9:00 am Check In; 10:00 am Walk Start Winterplace Park, Salisbury, MD

2016 Scientific Session

Thursday, May 5, 2016 6:00 pm – 9:00 pm Johns Hopkins Bayview Asthma & Allergy Center, Baltimore, MD

Rappel for Kidney Health

June 24-25, 2016 Hyatt Regency, Baltimore, MD

For more information about NKF-MD's programs or services, contact

Jessica Quintilian, Director of Field Services at 443-322-0375 or

jauintilan@kidneymd.org.

2015 Accomplishments For The Kidney Disease Program

The Kidney Disease Program (KDP) enhanced the Program's website with information and updates relative to the Program. The address of this website is http:// mmcp.dhmh.maryland.gov/familyplanning/ Pages/Kidneydisease.aspx. This website includes helpful information, such as: KDP Notices of updates/changes, Information Resources, Web Links, Phone Numbers, e-Mail Address for Questions about KDP, Billing Instructions, KDP COMAR Regulations and the KDP Drug Formulary. This website will undergo continuing development in an effort to provide the renal community with the most up to date information available with regard to the Kidney Disease Program. Enhancements and system developments to the KDP electronic claims management system (eCMS) and the Xerox pharmacy pointof-sale system (POS) continue in an effort to provide more efficient and timelier processing of claims. These systems continue to allow KDP to accept and return HIPAA compliant transactions from Medicare trading partners and all participating providers.

In addition, ESRD providers of service were granted access to the KDP Portal. The website, to gain access to the KDP portal is

www.dhmheclaims.org. This portal allows providers to verify a claims status and view detailed payment information, which includes, check numbers, check dates and voucher numbers. This information assists providers in maintaining an accurate and up to date accounts receivable system and minimizes duplicate billing. In addition, providers of service may access up to date eligibility information for all ESRD patients certified with the Kidney Disease Program of MD.

The Kidney Disease Program has developed and implemented the necessary requirements and crosswalk for the federally mandated ICD-10 conversion effective October 2015. The Program has completed all changes and updates to accommodate the new codes on the UB04 and CMS 1500 claim forms assuring that all claims will continue to be processed in a timely manner.

Santeon upgraded the entire eCMS platform to be compatible with newer Windows version and .Net frameworks. This upgrade has improved the security of the system as Microsoft is ending the support for older Windows versions and frameworks. Upgrading the entire eCMS platform improved the security, reliability and performance of eCMS thus enhancing the efficiency and productivity of the system.

The Kidney Disease Program worked with contractors to develop and implement the Medicaid Enterprise Restructuring Project (MERP). This project has since been terminated. In answer to the termination of MERP, KDP is pursuing a sole source contract with Santeon, the current KDP claims processing vendor, to continue the KDP claims functioning processes, financial payments and recoveries, in addition to reporting requirements. The contract being pursued will be a 5 year contract covering FY 2016 thru FY 2021.

Customer service in the areas of patient certification, accounts payable and accounts receivable continues to improve. KDP personnel strive to assist KDP recipients, in processing applications as quickly and efficiently as possible, adjudicate claims in a timely manner, provide assistance with program participation fees, and provide education to members of the renal community to assist them in receiving the most accurate information possible.